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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,460	07/18/2001	Lynn B. Lunsford	08191-014002	1198

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/02/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,460

Applicant(s)

LUNSFORD ET AL.

Examiner

Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-36, drawn to a polymeric composition comprising a polymer microparticle and DNA, wherein the polymeric microparticle is less than about 20 microns, and method of using the polymeric composition to deliver an encoded DNA molecule to a subject, classified in class 435, subclass 320.1, and Class 514, subclass 44.

Group II. Claims 37-51, drawn to a method of preparing an aqueous solution of DNA in a polymeric composition, wherein the steps of mixing solutions to produce a first emulsion, second emulsion, and third emulsion, wherein the shearing of the DNA is minimized, and wherein microparticles having an average diameter smaller than 100 microns, microparticles produced by the method, and DNA delivery method using the produced microparticles, are classified in class 435, subclass 320.1, class 424, subclass 468, and class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Group II and Group I are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, an aqueous solution containing a DNA of invention I can be encapsulated by a polymeric microparticle of Invention I by using conventional techniques such as interfacial microencapsulation, solvent extraction, and physical encapsulation. Thus, the polymeric compositions cited in Group I can be made by processes other than the process cited in Group II.

Claims 1-36 are generic to a plurality of disclosed patentably distinct species comprising:

- A/ a DNA encoding a naturally-occurring mammalian polypeptide;
- B/ a DNA encoding a peptide which binds to an MHC class I molecule;
- C/ a DNA encoding a peptide which binds to an MHC class II molecule;

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D/ a DNA encoding a naturally occurring protein from an infectious agent;

Should species A, B, C, or D be elected, item (d) will only be searched and examined to the extent that item (d) is encompassed by the elected species.

Should Group I be elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above (claim 8), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I, and the species of A, B, C, or D be elected, claim 9 is generic to a plurality of disclosed patentably distinct species comprising:

- A cationic lipid;
- An anionic lipid; and
- A zwitteronic lipid.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the lipid cited in claim 9, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I be elected, the disclosed species C be elected, claim 24 is generic to a plurality of disclosed patentably distinct species comprising:

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- A specific MHC II binding protein fragment of a specific protein as listed in claim 24.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the protein fragment cited in claim 24, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I be elected, the disclosed species B/ or C/ be elected, claims 8 and 25 are generic to a plurality of disclosed patentably distinct species comprising:

A specific DNA sequence as set forth in SEQ ID NOS 1-46. Note that an elected DNA sequence will be search and examined to the extent that the elected DNA sequence is encompassed by either the elected species B/ or species C/.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 25, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I, and species A, B, C, or D be elected, wherein item d) falls within the elected species A, B, C, or D, claim 26 is also generic to a plurality of disclosed patentably distinct species comprising:

- a sequence which trafficks to endoplasmic reticulum;

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- a sequence which trafficks to a lysosome;
- a sequence which trafficks to an endosome; and
- a sequence which trafficks to a nucleus.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 26, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I, and the disclosed species A/ be elected, claims 8, 27, and 28 are also generic to a plurality of disclosed patentably distinct species comprising:

A specific tumor antigen as listed in Table 3.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 28, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I, and the disclosed species D/ be elected, claims 8, 29-32 are also generic to a plurality of disclosed patentably distinct species comprising:

A protein essentially identical to a protein expressed by a specific infectious agent as listed in claims 29-32. For example, if a species of a virus is elected, Applicant is required to elect a specific virus as listed

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in claim 30-32.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in the claims, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER